JAN - 9 2001

K003457

510(k) summary

(As Required by Section 807.92 (c))

1. **Submitter**

Name:	Unicare Biomedical, Inc.
Address:	25951 La Cuesta Avenue, Laguna Hills, CA 92653
Contact:	Stan Yang, 949-362-1772
Date:	November 02, 2000

2. **Device Name**

Trade Name:	Unigraft®
Common Name:	Synthetic bone graft material
Classification Name:	Endosseous implant for bone filling and augmentation
Device Classification:	Unclassified

3. **Device Description**

Unigraft® is a synthetic bioactive glass that is intended for use in the repair of oral/maxillofacial and dental intraosseous defects. The bioactive glass (CaO, Na_2O, P_2O_5 and SiO_2) used in Unigraft® is manufactured as irregular shaped synthetic granules, sized from about 200 microns to about 420 microns. It is supplied sterile in a foil sealed polyolefin vial. The product is to be mixed with sterile saline or with patient's blood to form a sandy paste that is to be applied to the defect.

4. **Predicate Devices**

The Unigraft® device is substantially equivalent to devices currently in US commercial distribution, which are classified as endosseous implant for bone filling and augmentation. Examples of such products include PerioGlas® and BioGran®. These products are made of bioactive ceramic materials with similar performance.

5. **Intended Use**

Unigraft is intended to fill and/or augment dental intraosseous and oral/maxillofacial defects including:

Periodontal defects
Ridge augmentation
Extraction sites
Cranio-facial augmentation
Sinus lifts
Cystic defects

6. **Device Testing**

The performance of Unigraft® was evaluated using a variety of test methods. The results of these tests demonstrate that Unigraft® is substantially equivalent to a predicate device. The clinical results of Unigraft® are comparable to the published data of a predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2001

Mr. Stan Yang
Vice President
Unicare Biomedical
25951 La Cuesta Avenue
Laguna Hills, California 92653

Re: K003457
Trade Name: Unigraft
Regulatory Class: Unclassified
Product Code: LYC
Dated: November 3, 2000
Received: November 7, 2000

Dear Mr. Yang:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) NUMBER: K003457

DEVICE NAME: UNIGRAFT®

INDICATIONS FOR USE:

Unigraft® is intended to fill and/or augment dental intraosseous and oral/maxillofacial defects including:

~~periodontal defects~~,
sinus lifts,
cystic defects,
extraction sites,
~~cranio-facial augmentation and~~
augmentation of the alveolar ridge.

Concurrence of CDRH, Office of device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Susan Runner
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003457